

K964630

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510(k) SAFETY AND EFFECTIVENESS SUMMARY

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Device: Trade/Proprietary Name: GLUCOMETER ELITE® Blood Glucose Meter
Common/Usual Name: Blood Glucose Meter
Document Control Number: K96 _____

Classification: Division of Clinical Laboratory Devices
Panel - Clinical Chemistry and Toxicology
Classification Code - 75 CGA (Glucose Oxidase, Glucose)

Predicate Device: GLUCOMETER ELITE® Blood Glucose Meter
Manufactured by Kyoto Daiichi Kagaku Co., Ltd. of Kyoto, Japan

Device Description: The GLUCOMETER ELITE System consists of an electrochemical method-based meter and dry reagent sensors (test strips) designed for testing glucose by persons with diabetes or by healthcare professionals in the home or in healthcare facilities.

Intended Use: The GLUCOMETER ELITE Blood Glucose Meter is for the Self-Monitoring of Blood Glucose as an adjunct to the care of persons with diabetes.*

* "Consensus Statement on Self-Monitoring of Blood Glucose," *Diabetes Care*, Vol. 10, No. 1, January-February 1987, pp. 95-99.

**Technological
Characteristics:**

The electronics of the GLUCOMETER ELITE Blood Glucose Meter have been modified to reduce the time for obtaining a result from 60 to 30 seconds. The operating range has been expanded from 40 - 500 mg/dL to 20 - 600 mg/dL. The capacity of the read only memory (ROM) has been increased from retaining 10 results to 20 and improvements in calibration and temperature correction have been implemented. In addition, cosmetic changes to the case give the meter a new appearance and the test slot has been moved from the left side to the top of the meter.

**Assessment of
Performance:**

An evaluation of the modified GLUCOMETER ELITE Blood Glucose Meter was conducted at three clinical sites to demonstrate the equivalence of the modified meter to the currently used GLUCOMETER ELITE Blood Glucose Meter, the predicate device, in the hands of diabetics and healthcare professionals.

Conclusion:

The results of the evaluation of the GLUCOMETER ELITE Blood Glucose Meter demonstrate that the modified meter is equivalent in performance to the predicate device and suitable for its intended use.